June 9, 2005

1521 5 JUN -9 A10 :33

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

The undersigned submits this petition under section 403 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") and 21 C.F.R. § 10.30 to request the Commissioner of Food and Drugs to take administrative action.

A. ACTION REQUESTED

The Physicians Committee for Responsible Medicine ("PCRM") requests that the Commissioner of Food and Drugs:

(1) Institute an examination or investigation into the labeling of certain food products made and distributed by The Dannon Company, Inc., General Mills, Inc., McNeil Nutritionals, LLC, and any other parties ("dairy product manufacturers") that make unauthorized health claims regarding the purported weight and fat loss benefits of dairy products, pursuant to 21 U.S.C. § 372(a);

(2) Declare food products made and distributed by the dairy product manufacturers and bearing labels with unauthorized health claims regarding the purported weight and fat loss benefits of dairy products misbranded;

(3) Institute a voluntary recall, court-ordered injunction, or seizure of misbranded food products made and distributed by the dairy product manufacturers, pursuant to 21 U.S.C. § 332(a), 21 U.S.C. § 334(a)(1), 21 C.F.R. § 7.40, and 21 C.F.R. § 7.45; and

(4) As a corrective measure, require material disclosure of affirmative facts about the lack of a scientific connection between dairy consumption and weight and fat loss on future products made and distributed by the dairy product manufacturers, pursuant to 21 U.S.C. § 371 and 21 C.F.R. § 1.21(b).

To the extent that the U.S. Department of Agriculture ("USDA") and Federal Trade Commission ("FTC") have concurrent jurisdiction over the matter, PCRM requests that the Food and Drug Administration ("FDA") work with USDA and FTC officials to remedy the concerns raised in this petition.[1]

[1] In its Memorandum of Understanding with FDA, FTC confirmed its commitment to prevent deception of the public and took primary responsibility for preventing deceptive food advertising. *See* Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) ¶ 9851 (1971). To the extent USDA or FTC have primary jurisdiction, PCRM asks that FDA advise these agencies to take action.

2005P-0224

CP1

B. STATEMENT OF GROUNDS

1. Introduction

a. Background Information

Americans' per capita consumption of milk continues to decline, despite the vigorous efforts of the dairy industry to convince Americans to consume more milk. In December 2001, the *Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity* was released, warning that overweight and obesity have reached epidemic proportions in the United States, with an estimated 61 percent of adults overweight or obese and 13 percent of children and adolescents overweight.[2] The *Call to Action* also cautioned that hundreds of thousands of deaths per year in this country are currently associated with overweight and obesity, which, left unabated, may soon cause as much preventable disease and death as cigarette smoking.[3] Since that time, it seems that, more than ever before, everyone has tried to jump on the obesity-prevention bandwagon.

In April 2003, dairy advertisers "Joined Forces to Address the [Obesity] Opportunity," by holding a "joint strategy meeting."[4] In addition to using the obesity crisis as an impetus for the campaign, the meeting participants noted that the claim would be more likely to withstand FDA scrutiny because of FDA's new relaxed standards for making unproven health claims.[5] Thus, the "Healthy Weight with Dairy" weight loss promotion was born. This promotion is a multi-million dollar campaign comprised of many components, including national and regional print, television, and Internet advertising directed towards consumers and trade and health professionals, in-store and online promotions, celebrity spokespersons, distribution of weight loss guides, coupons, prize giveaways, a sweepstakes, and various mini-promotions, centered around the spurious health claim that consuming dairy products is an effective obesity prevention tool.

Several dairy product manufacturers have now adopted the message of the weight loss promotion—that consuming three servings of dairy per day leads to weight and fat loss—in health claims made on the labeling of their food products. They have done so without first obtaining the statutorily required FDA approval for the inclusion of health claims on labels. These food products therefore are misbranded, in violation of the FFDCA. The products also are misbranded because the labels are false and misleading[6] and fail to disclose material facts.[7] These health claims are based on studies performed on mice, thus inconsequential to a human health claim, and on very limited and unconfirmed human studies *that rely on caloric restriction* to show a weight loss. In fact, human studies in which individuals simply added dairy products

---

[2] *See* HHS, THE SURGEON GENERAL'S CALL TO ACTION TO PREVENT AND DECREASE OVERWEIGHT AND OBESITY XIII (2001) (attached as Ex. 1), http://www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf (last visited May 31, 2005).

[3] *Id*

[4] *See* Ex. 2.

[5] *Id*

[6] 21 U.S.C. § 343(a) (2005).

[7] *See id.* § 321(n); 21 C.F.R. § 1.21(a) (2005).

to their diet did not result in weight loss. Rather, in the absence of caloric restriction, dairy products have either had no effect at all or have even caused weight gain. Here, dairy product manufacturers have asserted a health claim that is not true, have failed to disclose pertinent information that contradicts their claim, and have not informed consumers of the actual diet required to achieve weight loss.

b. Parties

Petitioner PCRM is a nonprofit public health advocacy association located at 5100 Wisconsin Avenue, NW, Washington, DC, 20016, supported by more than 100,000 physician and layperson members. PCRM advocates for preventive medicine through good nutrition.[8]

The Dannon Company, Inc., is the manufacturer of Dannon yogurt. Dannon participated in the development of the weight loss promotion[9] and includes the following health claims on its Light 'n Fit nonfat yogurt[10]:

- "Slim Down with Yogurt. Lose more weight as part of a reduced calorie diet. See details under lid."
- The labeling underneath the lid states, "Dairy products, like Light 'n Fit yogurt, have been shown in studies to help you lose more weight and burn more fat than just cutting calories alone.*
  * 3-4 servings daily (providing at least 600 mg of calcium per day) as part of a high-calcium, reduced calorie diet. For details, visit www.dannon.com."

General Mills, Inc., manufactures Yoplait brand yogurt. General Mills also participated in the development of the weight loss promotion[11] and includes the following health claims on the labeling of its Yoplait "Original" yogurt[12] and Yoplait "Thick & Creamy" yogurt[13]:

- "Burn More Fat. Recent research shows that dairy foods, like Yoplait, may help you burn more fat and lose more weight than cutting calories alone.*
  * 3 servings of dairy daily in a reduced-calorie diet."
- "3-A-Day Milk Cheese Yogurt. Burn more fat, lose weight.*
  * In a reduced-calorie diet. See under lid for details."
- The labeling underneath the lid states, "As part of a reduced-calorie diet, 3 servings daily of dairy foods, like Yoplait, supports more weight loss than cutting calories alone."

---

[8] On April 21, 2005, PCRM filed a petition with FTC, seeking a determination that a series of similar dairy weight loss claims made in print, television, and Internet advertising by various dairy trade associations and dairy product manufacturers were false and misleading. The remedies sought were an injunction to prevent further dissemination of dairy weight loss advertisements, a permanent prohibition of such advertisements, and corrective advertising. A copy of PCRM's petition is attached as Exhibit 3.

[9] *See* Ex 2.

[10] *See* Ex. 4.

[11] *See* Ex. 2.

[12] *See* Ex. 5.

[13] *See* Ex. 6.

McNeil Nutritionals, LLC, manufactures Lactaid brand milk products. It includes the following health claims on the labeling of its Lactaid Whole Milk,[14] Reduced Fat Milk,[15] Lowfat Milk,[16] and Fat Free Milk[17] products:

- "3-A-Day Milk Cheese Yogurt. Burn more fat, lose weight. 3 servings of dairy a day in a reduced-calorie diet supports weight loss."
- "Losing Weight can be as simple as **1** a healthy reduced-calorie diet **2** exercise **3** servings of dairy a day."
- "Recent studies now suggest that having three servings of dairy, such as LACTAID Milk, each day in a reduced calorie diet may help support your healthy weight loss. Enjoying dairy three times a day. Now that's a great way to help you lose weight!"

c. Jurisdiction

FDA has jurisdiction over health claims made in the labeling of food products introduced into interstate commerce pursuant to section 301 of the FFDCA.[18]

2. Statutes and Regulations

FDA regulates the labeling of food products and dietary supplements under the Nutrition Labeling and Education Act of 1990,[19] which amended the FFDCA to prescribe nutrition labeling for foods. The FFDCA prohibits the misbranding of food and the introduction of misbranded food into interstate commerce.[20] A food product is considered misbranded if its labeling contains a health claim that is not made in accordance with the requirements of the statute[21] or if "its labeling is false or misleading."[22]

a. Health Claims

A health claim is a claim "made on the label or in labeling of a food . . . that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition."[23] An express health claim directly makes a representation.[24] An implied health claim is one that suggests that a relationship exists between the presence or level of a substance in the

---

[14] *See* Ex. 7.
[15] *See* Ex. 8.
[16] *See* Ex. 9.
[17] *See* Ex. 10.
[18] *See* 21 U.S.C. § 331 (2005).
[19] National Labeling and Education Act of 1990, Pub. L. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).
[20] 21 U.S.C. § 331(a)–(b) (2005).
[21] *Id* § 343(r)(1)(B). *See also* 21 C.F.R. § 101.14 (2005).
[22] 21 U.S.C. § 343(a) (2005).
[23] 21 C.F.R. § 101.14 (2005).
[24] FTC Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388 (June 1, 1994) (issued by FTC after passage of NLEA in order to "harmonize [FTC's] advertising enforcement program with FDA's food labeling regulations to the fullest extent possible") (attached as Ex. 11), http://vm.cfsan.fda.gov/~lrd/ftcfood.txt (May 13, 1994).

food and a disease or health-related condition.[25]

Section 403 of the FFDCA provides two methods through which FDA allows food product manufacturers to make health claims in food labeling. In the first method, the manufacturer may make a health claim if the claim is authorized by FDA regulations[26] upon a finding of "significant scientific agreement."[27] This "significant scientific agreement" standard is based on a body of sound and relevant scientific data and is intended to provide a high level of confidence that the validity of the substance/disease relationship is not likely to be reversed by new and evolving science.[28] Thus, these "unqualified" health claims require significant scientific agreement based on the totality of publicly available scientific evidence.[29]

The second method allows a manufacturer to label a food product with a health claim that is based on an authoritative claim by certain scientific bodies of the federal government or the National Academy of Sciences or any of its subdivisions.[30] Before doing so, however, the manufacturer must provide notification to FDA of its intention to use the health claim 120 days in advance.[31] The notification must include the specific wording of the health claim and a summary of the science behind the claim.[32] The wording of the health claim must accurately reflect the authoritative statement by the approved scientific body and must not be confusing to the public.[33] This type of health claim also requires FDA approval.[34] Health claims approved through this process and under the scientific agreement standard are listed at the FDA Web site[35] and in the Code of Federal Regulations.[36]

Recently, FDA issued interim regulatory guidance[37] allowing lower standards of proof for the substantiation of substance/disease relationships that are the subject of "qualified" health

---

[25] 21 C.F.R. § 101.14 (2005).

[26] 21 U.S.C. § 343(r)(3)(A)(i) (2005).

[27] The Secretary must first determine "based on the totality of publicly available scientific evidence . . . that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." *Id.* § 343(r)(3)(B)(i). *See also* 21 C.F.R. § 101.14(c) (2005).

[28] CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, GUIDANCE FOR INDUSTRY: SIGNIFICANT SCIENTIFIC AGREEMENT IN THE REVIEW OF HEALTH CLAIMS FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (1999), http://www.cfsan.fda.gov/~dms/ssaguide.html (Dec. 22, 1999).

[29] *Id*

[30] 21 U.S.C. § 343(r)(3)(C)(i) (2005).

[31] *Id.* § 343(r)(3)(C)(ii).

[32] *Id*

[33] *See id* § 343(r)(3)(C)(iv).

[34] *Id* § 343(r)(3)(D)(i); 21 C.F.R. §§ 101.14(c), (e) (2005).

[35] CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, A FOOD LABELING GUIDE–APPENDIX C (2003), http://www.cfsan.fda.gov/~dms/flg-6c.html (last updated May 13, 2003).

[36] Each authorized health claim is listed as a separate regulation in title 21, chapter I, subchapter B, part 101, subpart E. 21 C.F.R. § 101.14(d) (2005). *See id.* §§ 101.72–101.83.

[37] *See* CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, INTERIM PROCEDURES FOR QUALIFIED HEALTH CLAIMS IN THE LABELING OF CONVENTIONAL HUMAN FOOD AND HUMAN DIETARY SUPPLEMENTS (2003), http://www.cfsan.fda.gov/~dms/hclmgui3.html (last updated Nov. 10, 2003). While these interim guidelines are not legally enforceable because they have not been promulgated through notice-and-comment rulemaking, they do set forth the Agency's intended course of action for regulations. As of this date, FDA has not issued proposed or final regulations on this subject, but it did issue an Advanced Notice of Proposed Rulemaking. *See* Food Labeling: Health Claims; Dietary Guidance, 68 Fed. Reg. 66,040 (Nov. 25, 2003) (to be codified at 21 C.F.R.).

claims.[38] Under the interim guidelines, qualified health claims are appropriate "when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition."[39] Pursuant to this guidance, food manufacturers may petition for the right to use qualified health claims that are worded ("qualified") in such a way that consumers are not misled about the nature of the supporting science.[40] FDA will approve a petition for a qualified health claim only after performing a scientific review of the claim and determining what accompanying qualifying language must be included before the claim may be used.[41] The FDA Web site includes a list of currently authorized qualified health claims.[42]

Health claims cannot be made for food products that contain nutrients that increase the risk of a disease or health-related condition that is related to diet, unless specifically allowed by FDA regulation.[43] This is because FDA regulations recognize that the consumption of fat, saturated fat, cholesterol, and sodium are associated with an increased risk of certain diseases and health-related conditions, particularly cancer, cardiovascular disease, and hypertension.[44] Thus, FDA regulations prohibit any health claim in the labeling of foods that contain a pre-established level of total fat, saturated fat, cholesterol, or sodium.[45] For instance, if a food has more than 13 grams of fat, 4 grams of saturated fat, or 60 milligrams of cholesterol per serving, no health claim can be made on the label of that food product unless a regulatory exception is provided.[46]

b. False and Misleading Labeling

A food product is misbranded if any one representation on its labeling is either false or misleading.[47] Labeling is considered misleading if it fails to reveal facts that are material either in light of other statements or suggestions on the label or with respect to consequences that result under the prescribed or customary use of the food.[48] FDA employs the "reasonable consumer" standard for assessing whether a food label is misleading.[49] Although FDA has not published a

---

[38] FDA adopted this policy in response to court rulings establishing that consumers have a First Amendment right to truthful health information even if that information is not supported by significant scientific agreement. *See Pearson v Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

[39] CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, CLAIMS THAT CAN BE MADE FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (2003), http://www.cfsan.fda.gov/~dms/hclaims.html (last updated Sep. 24, 2003).

[40] *Id*

[41] A FOOD LABELING GUIDE–APPENDIX C, *supra* note 35 (explaining the review process in sections B.4, B.7, and B.8).

[42] CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, SUMMARY OF QUALIFIED HEALTH CLAIMS PERMITTED (2003), http://www.cfsan.fda.gov/%7Edms/qhc-sum.html (last updated Dec. 9, 2004).

[43] 21 U.S.C. § 343(r)(3)(A)(ii) (2005).

[44] 21 C.F.R. §§ 101.73–101.75 (2005).

[45] *Id.* § 101.14(a)(4).

[46] *Id. See also id* § 101.14(e)(3).

[47] 21 U.S.C. § 343(a) (2005). *See also United States v. Hoxsey Cancer Clinic*, 198 F.2d 273, 281 (5th Cir. 1952) ("It was not necessary for the Government to prove that each and every representation in the booklet was false or misleading. The statute seeks to prevent labeling which is false or misleading in any particular.").

[48] 21 U.S.C. § 201(n) (2005); 21 C.F.R. § 1.21(a) (2005).

[49] *See* Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed. Reg. 78,002, 78,003 (Dec. 20, 2002) (adopting the "reasonable consumer"

deception policy statement, it favorably cited the *FTC Policy Statement on Deception*[50] when it adopted the reasonable consumer standard.[51] This policy considers a health claim from the perspective of a consumer acting reasonably under the circumstances.[52] Under the policy, a statement that can be reasonably interpreted in a misleading way is deceptive, even though other, non-misleading interpretations may be equally possible.[53] Furthermore, an interpretation is presumed reasonable if it is the claim the food product manufacturer attempted to convey.[54]

3. Argument

a. Dairy Product Manufacturers' Dairy Products Are Misbranded Because Approval for the Dairy/Weight Loss-Obesity Prevention Health Claims Has Not Been Sought or Obtained

Dairy product manufacturers basically make two obesity-prevention claims: that the consumption of dairy products will cause *weight* loss and that the consumption of dairy products will cause *fat* loss. These claims are "health claims" that have not been approved by FDA.

"Health claims" characterize the relationship between a substance and its ability to reduce the risk of a disease or health-related condition.[55] A "substance" means a specific food or component of food.[56] "Disease" or "health-related condition" means damage to an organ, part, structure, or system of the body such that it does not function properly or a state of health leading to such dysfunctioning.[57]

Milk and yogurt are "substances" because they are specific foods. Calcium is also a "substance" because it is a component of milk and yogurt. Moreover, obesity is a disease and a health-related condition. Recently, the IRS began recognizing obesity as a disease,[58] and Medicare redefined obesity as an illness.[59] The *Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity* noted that the health consequences of overweight and obesity is "a public health issue that is among the most burdensome faced by the Nation . . . . This burden manifests itself in premature death and disability, in health care costs, in lost productivity, and in social stigmatization. The burden is not trivial. Studies show that the risk of death rises with increasing weight. Even moderate weight excess . . . increases the risk of death."[60] Moreover, the Surgeon General noted, overweight and obesity are associated with premature death, type 2

---

standard to make FDA's regulation of food labeling consistent with FTC's regulation of advertising for the same products and to ensure that FDA's approach is consistent with First Amendment case law).

[50] FTC, FTC POLICY STATEMENT ON DECEPTION (1983) (attached as Ex. 12), http://www.ftc.gov/bcp/policystmt/ad-decept.htm (last visited Apr. 28, 2005).

[51] *See* Guidance for Industry, *supra* note 49, at 78,003–04.

[52] FTC POLICY STATEMENT ON DECEPTION, *supra* note 50.

[53] *Id*

[54] *Id.*

[55] 21 C.F.R. § 101.14 (2005).

[56] *Id* § 101.14(a)(2).

[57] *Id* § 101.14(a)(5).

[58] *See* IRS, DEP'T OF TREASURY, PUBLICATION 502 (2004) (attached as Ex. 13).

[59] Marguerite Higgins, *Obesity Deemed an Illness*, WASH. TIMES, July 15, 2004 (attached as Ex. 14), http://www.washingtontimes.com/business/20040715-104805-1408r.htm (last visited Apr. 28, 2005).

[60] THE SURGEON GENERAL'S CALL TO ACTION, *supra* note 2, at 1.

diabetes, heart disease, stroke, hypertension, gallbladder disease, osteoarthritis, sleep apnea, asthma, breathing problems, and cancer (endometrial, colon, kidney, gallbladder, and postmenopausal breast), among other health dysfunctions.[61]

Thus, the dairy/weight and fat loss claims are health claims that must be approved by FDA. However, there has been no authoritative claim by a scientific body of the federal government or the National Academy of Sciences on which to base such health claims. Furthermore, FDA has not authorized, as unqualified or qualified, health claims that consuming three servings of dairy products or three servings of dairy calcium—or for that matter, calcium from any source—leads to a greater likelihood of weight loss or fat loss, nor have the dairy product manufacturers petitioned FDA for either a qualified or unqualified health claim related to the dairy/weight and fat loss hypothesis.[62] Even if the dairy product manufacturers had petitioned for approval to make these health claims, FDA would undoubtedly have denied such petitions because the scientific evidence in support of the claims would fail to meet even the lowest standard set forth by FDA.[63] Factoring in the failure of dairy product manufacturers to seek approval before placing these health claims on food product labeling, the absence of an FDA determination that these claims are scientifically valid, and the absolute lack of reliable scientific support for these claims, FDA must find that the products labeled with such health claims are misbranded, in violation of section 301 of FFDCA.

b. Dairy Product Manufacturers' Dairy Products Are Misbranded Because Their Labels Carry Health Claims that Are False and Misleading to the Reasonable Consumer

i. The Body of Scientific Evidence Does Not Support the Claim that Dairy Products Reduce the Risk of Obesity or Cause Greater Weight Loss than Just Cutting Calories Alone

Dairy product manufacturers claim that dairy products facilitate weight control, citing what they characterize as "recent research"[64] or "recent studies"[65] that they assert support this claim. The body of scientific evidence, including emerging science, however, supports precisely the opposite conclusion: studies show that adding dairy products to the diet does nothing whatsoever for weight control; in some cases, it encourages weight *gain*. Thus, any labeling bearing such health claims is false and products so labeled are misbranded[66] in violation of the FFDCA.

Dairy product manufacturers rest their claim on the findings of a single industry-funded experimenter whose studies are small, poorly controlled, and reported with only minimal detail,

---

[61] *Id* at 9 tbl.1.

[62] This conclusion is based on a review of FDA's Web site, which lists all petitions submitted for approval of both unqualified and qualified health claims. *See* FDA, DOCKETS MANAGEMENT, *at* http://www.fda.gov/ohrms/dockets/ (last visited June 7, 2005); FDA, QUALIFIED HEALTH CLAIMS, *at* http://www.cfsan.fda.gov/~dms/lab-qhc.html#petition (last visited June 7, 2005).

[63] *See* CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FDA, INTERIM EVIDENCE-BASED RANKING SYSTEM FOR SCIENTIFIC DATA (2003), http://www.cfsan.fda.gov/~dms/hclmgui4.html (last updated Nov. 10, 2003).

[64] Exs. 5–6.

[65] Exs. 7–10.

[66] 21 U.S.C. § 343(a) (2005).

yielding inconsistent results. This researcher, Michael Zemel, Ph.D., of the University of Tennessee, Knoxville, consistently fails to report the calorie intake of research participants, making it impossible to assess whether differences in caloric intake alone are responsible for any changes in weight. Some of his reports are abstracts only, rather than full reports, making it impossible to fully assess his methods or data set. Dr. Zemel has a financial stake in the outcome of these studies. Not only did he receive grants from the National Dairy Council, which is the nutrition marketing arm of a dairy industry trade association that promotes demand for U.S. dairy products, and the breakfast cereal and yogurt industries, including General Mills, to do his studies,[67] but he also holds a patent with the U.S. Patent and Trademark Office to the method of using calcium and/or dairy products for the treatment and prevention of obesity.[68]

Dr. Zemel's findings have not been replicated by other researchers using similar methods and are not representative of the body of research. Even some of Dr. Zemel's results are contrary to the dairy product manufacturers' claims, showing that dairy product consumption does not facilitate weight loss.

The following is a summary of the body of science evaluating the question whether dairy product consumption, either with or without a reduction in energy intake, will prevent obesity or facilitate weight loss.[69] Scientific studies have tested the effect of dairy product or calcium supplement consumption on body weight in both the presence and absence of calorie restrictions, and these studies are described below. In either case, the evidence fails to show or lend support to the claim that dairy product or calcium consumption improves weight control or results in weight or fat loss.

a) Clinical Studies on Dairy Products or Calcium Supplements Without Energy Restriction

Barr (2003)[70] of the University of British Columbia reviewed the scientific literature on the effect of dairy products or calcium supplements on bone health. These studies also adduced findings on body weight. Of 26 studies reviewed, 9 involved dairy products and 17 involved calcium supplements.

Of the nine dairy trials, two showed an *increase* in body weight in the dairy groups, compared to the non-dairy groups, whereas seven showed no difference in body weight (including BMI) or adiposity. None showed any weight improvement whatsoever.

---

[67] *See* CENTER FOR SCIENCE IN THE PUBLIC INTEREST, THE INTEGRITY IN SCIENCE DATABASE (2005) (attached as Ex. 15), *at* http://www.cspinet.org/integrity/ (last visited May 31, 2005)

[68] *See* Zemel patent information, attached as Exhibit 16.

[69] Please note that the first time a study is identified in the body of this petition, it will be presented in bold; if it is referenced again, it will be in unbolded text. All medical studies will be cited according to the citation format recommended by the *American Medical Association Manual of Style*. All cited medical studies are attached as Exhibit 24.

[70] Barr SI. *Increased dairy product or calcium intake: Is body weight or composition affected in humans?* J Nutr. 2003;133:245S-248S.

In the 17 calcium supplementation trials, 16 showed that changes in body weight or body fat (where noted) were similar between the calcium-supplemented and the unsupplemented control groups. Only one study found greater weight loss in the calcium-supplemented group. This trial did not use dairy products as the treatment.

Of these 26 studies, 10 adduced data on body fat. Of these, none showed any difference in body fat change between high-dairy or high-calcium treatment groups and the untreated or low-dairy-consuming control groups.

After the publication of Dr. Barr's review, three additional studies addressed the effect of dairy or calcium on body weight. None reported an effect of dairy or calcium intake on body weight or body fat in the absence of caloric restriction. These studies are described below:

Wosje (2004)[71] studied the effect of calcium supplementation on weight and body fat in lactating and non-lactating women post-partum. Like the 26 studies reviewed by Barr, Wosje reported that supplementation with one gram/day of calcium did not promote weight or fat loss.

Lappe (2004)[72] tested the effect of dairy products on body weight in 59 pubertal girls who were assigned to either high-dairy or usual dairy intake diets and were followed for 2 years. Because gradual weight gain is normal during childhood and adolescence, the study helped address the question of whether the addition of dairy products has any ability to prevent obesity or excessive weight gain. The study showed that the girls in the two groups gained weight at the same rate, contradicting the claim that dairy products lead to weight control or play any role in determining fat deposition.

Gunther (2005)[73] assessed the effects of dairy products on weight in nonobese women (women more than 20 percent overweight were excluded). In the one-year study, participants were assigned to one of three groups: (1) a control group that maintained its usual diet, (2) a medium-dairy group consuming 1000–1100 mg of calcium daily, or (3) a high-dairy group consuming 1300–1400 mg of calcium daily. Participants in the two dairy groups were instructed to compensate for the addition of dairy products by reducing consumption of other foods so as to keep their energy intake unchanged. None of the groups lost weight. In fact, the high-dairy group gained 1.5 kg (3.3 lb) over the year, which was slightly (although not statistically significantly) greater than the weight gain in the control group (0.8 kg, 1.8 lb) and the medium-dairy group (0.7 kg, 1.5 lb).

The high-dairy group also gained more body fat, on average, than the other groups (0.5 kg fat gain in the high-dairy group, compared to a 0.3 kg fat gain in the medium-dairy group, and a 0.5 kg fat loss in the control group), although the differences were not statistically significant.

---

[71] Wosje KS, Kalkwarf HJ. *Lactation, weaning, and calcium supplementation: effects on body composition in postpartum women.* Am J Clin Nutr. 2004;80:423-429.

[72] Lappe JM, Rafferty KA, Davies M, Lypaczewski G. *Girls on a high-calcium diet gain weight at the same rate as girls on a normal diet: a pilot study.* J Am Diet Assoc. 2004;104:1361-1367.

[73] Gunther CW, Legowski PA, Lyle RM, et al. *Dairy products do not lead to alterations in body weight or fat mass in young women in a 1-y intervention.* Am J Clin Nutr. 2005;81:751-756.

Dairy products clearly did not facilitate weight loss. In fact, if the high-dairy group's experience continued in a similar fashion over a 10-year period, the average group member would have had a 15-kg (33-lb) weight gain, from the average baseline weight of 62.4 kg (137 lb) to 77.4 kg (170 lb), leading to an average body mass index of 27.8, which puts the group well into the overweight range (BMI > 25). The control group's 10-year experience, if similar to the one-year result, would have been a gain of about half as much weight as the high-dairy group.

This study is particularly relevant because the researchers asked the participants to add dairy products and, simultaneously, to watch their caloric intake. Specifically, participants were asked to reduce consumption of nondairy foods, which is similar to the message consumers may glean from some of the labeling in question.

Recently, **Huang (2005)**[74] reviewed both clinical and observational evidence linking dairy intake and obesity in children and adolescents, noting that "collectively, findings across studies fail to demonstrate compellingly a beneficial effect of dairy intake [on body weight or metabolic health] in children and adolescents." Reviewing evidence on body weight in these age groups, the authors noted, "all of the intervention studies to date have not shown any effect of dairy." Further, they pointed out that, although some previous authors have hypothesized that dairy consumption might influence body weight or fatness based on findings of some observational studies, such observations may be attributable to lack of control of confounding variables, such as total calorie intake and sweetened beverage intake.

In summary, no scientific studies support the existence of any weight-loss benefit from the addition of dairy products to the diet in the absence of a calorie restriction. One study, conducted by Dr. Zemel and described below, suggested that, in his participant sample, body fat was lost with milk supplementation without caloric restriction, despite the absence of any effect on body weight. No studies have corroborated this finding.

b) Studies on Dairy Products or Calcium Supplements with Energy Restriction

Seven studies have examined the question of whether dairy products or calcium supplements facilitate weight loss in the context of a reduced-calorie diet (five studied dairy products; two used calcium supplements). These studies are described below. Because dairy product manufacturers have based their claim primarily on Dr. Zemel's research, which has financial ties to the industries involved and has serious methodological problems, we will give special consideration to his studies.

Four of these studies were not conducted by Dr. Zemel (Harvey-Berino (2004), Bowen (2004), Shapses (2004), and Jensen (2001)). None showed any effect of dairy products or calcium supplements on body weight.

---

[74] Huang TTK, McCrory MA. *Dairy intake, obesity, and metabolic health in children and adolescents knowledge and gaps*. Nutr. Reviews 2005;63:71-80.

than the high-calcium group, contradicting the hypothesis that calcium facilitates weight loss. Those in the high-dairy group reportedly lost more fat (4.4 kg) than those in the low-calcium (2.7 kg) or high-calcium (2.2 kg) groups).

Zemel (2004b).[81] Dr. Zemel reported on the weight lost over 24 weeks by 32 obese individuals assigned to three different calorie-restricted diets: low-dairy/low calcium, high-dairy/high-calcium, and low-dairy/high-calcium. All participants were instructed to restrict daily caloric intake by 500 calories. Average weight loss was 6.6 kg for the low-dairy/low-calcium group, 11.1 kg for the high-dairy/high-calcium group, and 8.6 kg for the low-dairy/high-calcium group. Average body fat loss was 4.8 kg for the low-dairy/low-calcium group, 7.2 kg for the high-dairy/high-calcium group, and 5.6 kg for the low-dairy/high-calcium group.

Like all of Dr. Zemel's studies, this study is severely flawed by the failure to report the caloric intake of the participants and how it might have changed during the study because a change in caloric intake is the most likely reason for weight change. The weight loss of the high-dairy/high-calcium group, about one pound per week, is consistent with what is expected when a dieter reduces caloric intake by 500 calories per day.[82] The low-dairy/low-calcium and low-dairy/high-calcium groups lost on average about one-half pound per week, which is lower than would have been expected if the subjects actually maintained a 500-calorie/day deficit. These findings suggest that differences in weight loss may have been due, not to dairy use, but to differences in calorie intake. Nothing in Dr. Zemel's reported data would contradict such an interpretation.

Zemel (2005).[83] In this 12-week study, 34 obese adults were assigned to either an experimental weight-loss diet including 1100 mg of calcium per day contributed by yogurt or to a diet that was generally similar, but limited calcium to 500 mg per day. The experimental group lost, on average, 6.6 kg, compared to 5.0 kg in the control group (Dr. Zemel reported a P-value of "< 0.01", meaning there is less than a one-in-100 chance that the observed weight-loss difference is due to chance; this statistical finding cannot be verified). The loss of body fat was also reportedly greater in the experimental group. As in Dr. Zemel's other trials, the change in calorie intake of participants is not reported. This fact makes it impossible to discount the most likely reason for weight or fat loss—a reduction in calories having nothing to do with the consumption of dairy products.

---

[81] Zemel MB, Thompson W, Milstead A, Morris K, Campbell P. *Calcium and dairy acceleration of weight and fat loss during energy restriction in obese adults*. Obes Res. 2004;12:582-590.

[82] AMERICAN HEART ASSOCIATION, BE SMART FOR YOUR HEART (2005) (attached as Ex. 17), *at* http://www.americanheart.org/presenter.jhtml?identifier=502 (last visited May 31, 2005).

[83] Zemel MB, Richards J, Mathis S, Milstead A, Gebhardt L, Silva E. *Dairy augmentation of total and central fat loss in obese subjects*. Int J Obes. 2005;29:391-397.

d) Observational Studies[84]

Observational studies have been conducted on the associations between calcium or dairy products and body weight and/or adiposity. None of these observational studies has shown any association between dairy or calcium intake and weight or fat loss. Indeed, none has observed weight or fat loss at all. Some have observed associations with reduced rate of weight gain or with lower weight or adiposity at a single time point for some participant subgroups, but none supports the dairy product manufacturers' claim that dairy products will in any way facilitate weight or body fat loss.

It should be noted that although observational studies play an important role in the research process, they are not designed to show cause and effect and are subject to confounding. For example, some people consume dairy products because they are trying to adhere to what they believe is a healthful diet. These same individuals also tend to follow recommendations regarding reducing fat consumption, increasing fruits and vegetables in the diet, eating fiber-rich foods, and getting regular exercise, making it difficult to assess the role of dairy products or calcium in this context. For that purpose, randomized clinical trials are more helpful.

The demonstration of a weight-reducing effect of dairy products in prospective observational studies, had such a finding ever been adduced, would have been helpful for the dairy product manufacturers' claims, but still would not be sufficient to establish such claims. To illustrate this point, we recall the evolution of research data on hormone replacement therapy. In observational studies, estrogen/progesterone preparations were associated with reduced risk of heart disease. However, researchers feared that this association may not have been due to the hormones, but rather to the fact that women taking hormones were generally more health-conscious than other women and may have been more likely to adhere to healthful medical and lifestyle practices. Therefore, large randomized clinical trials were conducted, and they showed that, in fact, estrogen/progesterone combinations caused an *increased* risk of heart disease.

A similar situation exists regarding the use of dairy products or calcium supplements in relation to body weight. Because these products have been heavily promoted for their supposed health benefits, prospective observational health studies are affected by the fact that individuals using these products are more likely to be health-conscious, compared to those who are not. This does not discount the value of prospective studies, but clearly limits their interpretation.

To date, ten observational studies investigating the relationship between calcium or dairy intake and body weight have been published in report form (as opposed to abstract form). None of these studies showed weight loss over time in any population group. Of five studies conducted with

---

[84] Observational research is non-experimental research. Observational studies may be based on documentation in archived health records or patient databases maintained by states, insurers, departments, or researchers, or may be created prospectively. In these kinds of studies, it is not possible to determine a cause-effect relationship because the researcher does not control the variables. It might be possible to find correlations between observed variables, but this does not indicate the direction of a cause. *See* OBSERVATIONAL RESEARCH (attached as EX. 18), *at* http://web.isp.cz/jcrane/IB/Observations.html (last visited Apr. 28, 2005).

adults, three (**Lovejoy (2001)**,[85] **Loos (2003)**,[86] **Jacqmain (2003)**[87]) reported no relationship between calcium or dairy products and body weight in some subpopulations and an inverse relationship in others, one (**Mirmiran (2005)**[88]) reported an inverse relationship between dairy consumption and body mass index, and the fifth (**Lin (2000)**[89]) observed a smaller weight gain in those consuming more dietary calcium. Two studies in adolescents (**Phillips (2000)**,[90] **Novotny (2004)**[91]) showed no relationship between dairy intake or dietary calcium and body weight, while two studies in children (**Barba (2005)**,[92] **Tanasescu (2000)**[93]) showed an inverse relationship between these two factors. A very recent well-controlled longitudinal study by Dr. **Berkey (2005)**[94] and her Harvard colleagues of 121,829 adolescents followed yearly for 4 years showed that children who drank the most milk gained more weight than those who consumed less. The authors stated that "the added calories appeared to be responsible" for this excess weight gain.[95]

Of eight studies relating calcium or dairy intake to body fat (as opposed to body weight) in adults, adolescents, and children, four (Lin (2000), Novotny (2004), **Carruth (2001)**,[96] **Skinner (2003)**[97]) observed an inverse relationship, three (Lovejoy (2001), Loos (2003), Jacqmain (2003)) showed an inverse relationship with some subpopulations, but no relationship with others, and one observed no relationship (**Phillips (2003)**[98]).

As noted above, in none of these observational studies was dairy or calcium intake associated with weight or fat loss, and in at least one study milk consumption was associated with higher weight gain in adolescents; none supports the dairy product manufacturers' claims that dairy consumption facilitates weight or fat loss. Rather, inverse associations, when observed in

---

[85] Lovejoy JC, Champagne CM, Smith SR, de Jonge L, Xie H. *Ethnic differences in dietary intakes, physical activity, and energy expenditure in middle-aged, premenopausal women: the Healthy Transitions Study.* Am J Clin Nutr. 2001;74:90-95.

[86] Loos R, Rankinen T, Leon A, et al. *Calcium intake and body composition in the HERITAGE Family Study.* Obes Res. 2003:11(S):597-P.

[87] Jacqmain M, Doucet E, Despres JP, Bouchard C, Tremblay A. *Calcium intake, body composition, and lipoprotein-lipid concentrations in adults.* Am J Clin Nutr. 2003;77:1448-1452.

[88] Mirmiran P, Esmaillzadeh A, Azizi F. *Dairy consumption and body mass index: an inverse relationship.* Int J Obesity. 2005;29:115-121.

[89] Lin YC, Lyle RM, McCabe LD, McCabe GP, Weaver CM, Teegarden D. *Dairy calcium is related to changes in body composition during a two-year exercise intervention in young women.* J Am Coll Nutr. 2000;19:754-760.

[90] Phillips SM, Bandini LG, Cry H, Colclough-Douglas S, Naumova E, Must A. *Dairy food consumption and body weight and fatness studied longitudinally over the adolescent period.* Int J Obes. 2003;27:1106-1113.

[91] Novotny R, Daida YG, Acharya S, Grove JS, Vogt TM. *Dairy intake is associated with lower body fat and soda intake with greater weight in adolescent girls.* J Nutr. 2004;134:1905-1909.

[92] Barba G, Troiano E, Russo P, Venezia A, Siani A. *Inverse association between body mass and frequency of milk consumption in children.* Brit J Nutr. 2005;93:15-19.

[93] Tanasescu M, Ferris AM, Himmelgreen DA, Rodriguez N, Perez-Escamilla R. *Biobehavioral factors are associated with obesity in Puerto Rican children.* J Nutr. 2000;130:1734-1742.

[94] Berkey CS, Rockett HRH, Willett WC, Colditz GA. *Milk, dairy fat, dietary calcium, and weight gain: a longitudinal study of adolescents.* Arch Pediatr Adolesc Med 2005;159:543-550.

[95] *Id* at 543.

[96] Carruth BR, Skinner JD. *The role of dietary calcium and other nutrients in moderating body fat in preschool children.* Int J Obes. 2001;25:559-566.

[97] Skinner JD, et al. *Longitudinal calcium intake is negatively related to children's body fat indexes.* J Am Diet Assoc. 2003;103:1626-1631.

[98] Phillips (2003).

observational studies, were with lower weight and body fat at a single point in time or with reduced rate of weight or body fat gain only.

c) Summary of Research Findings

In summary, the body of scientific research contradicts dairy product manufacturers' health claims. Nearly all studies that have investigated an effect of dairy product consumption on weight change over time have found that dairy consumption either increases body weight or has no effect.

Of the 29 clinical trials not using caloric restriction that were not conducted by Dr. Zemel—26 studies reviewed by Barr and 3 studies published subsequent to her review—28 showed either weight gain or no effect on body weight. Only one (using calcium supplements, rather than dairy products) suggested any effect on body weight. No studies showed any effect on body fat.

Of the four randomized clinical trials not conducted by Dr. Zemel using a caloric restriction along with dairy products or calcium supplements, none showed any effect on body weight or body fat.

Only one researcher—who has a financial stake in the outcome—showed a statistically significant effect of dairy product consumption on weight loss and only when paired with a strict caloric restriction. His one abstract on the use of dairy products without caloric restriction showed no weight loss, but did report a differential loss of body fat. Two of his three reports using a strict caloric restriction along with the consumption of dairy products described weight loss and all three reported fat loss in the dairy groups. However, his reports are methodologically flawed, have not been replicated by others, have reported results that diverge from the rest of the body of relevant research, and exist only as two abstracts and two reports with incomplete data. In studies not carried out by that author, the body of research clearly shows that neither calcium-supplementation nor increased dairy product supplementation promote statistically significant weight loss or loss of body fat, either in the presence or absence of caloric restriction.

Prospective observational studies have not shown dairy products or calcium supplements to be associated with loss of body weight or body fat. In one large longitudinal study, higher milk consumption was associated with increased weight gain in adolescents. In some subgroups of some studies, dairy or calcium use has been associated with slowed rate of gain of weight or body fat over time or with lower weight or body fat at a single time point. Such associations, however, may relate to other dietary and lifestyle factors, and cannot be causally attributed to dairy products or calcium.

ii. Dairy Product Manufacturers Distort and Omit the Results of Relevant Scientific Research

An examination of the studies cited by dairy product manufacturers reveals that they have distorted the results and significance of the studies, in both the characterization and presentation of the data, and have omitted relevant studies that refute their claims. Such distortions and omissions give a false and misleading impression to the reasonable consumer about the scientific

validity of the claims that the daily consumption of three servings of dairy products in a reduced-calorie diet will result in weight or fat loss.

- *Dairy product manufacturers include studies irrelevant to the dairy/weight loss hypothesis.* The Lactaid Web site[99] cites **Layman (2003)**[100] and **Pereira (2002)**,[101] neither of which studied or reported on whether dairy products have any relationship with weight or body fat. The Yoplait Web site[102] also cites Pereira (2002). Additionally, the Lactaid Web site links to the Web site of the National Dairy Council,[103] which cites, Layman (2003) and Pereira (2003) as well as **Albertson (2003)**,[104] another study that did not even investigate or report on whether dairy products have any relationship with weight or body fat. The Lactaid Web site also links to the "24/24 milk your diet" weight loss plan Web site,[105] which cites the same three studies. Such inclusion of irrelevant sources in the supporting science exaggerates and distorts the truth to the reasonable consumer.

- *Dairy product manufacturers rely on review articles that merely summarize other studies.* The Lactaid Web site cites **Heaney (2003)**[106] and the Yoplait Web site cites **Teegarden (2003)**[107] and **Davies (2000)**,[108] all three of which are review articles that merely review previous studies. Additionally, the Lactaid Web site links to the Web sites of the National Dairy Council and the "24/24 milk your diet" weight loss plan, which cite seven review articles[109] and five review articles[110] respectively. Review papers

---

[99] LACTAID, DAIRY'S ROLE IN WEIGHT LOSS; A CLOSER LOOK AT THE SCIENCE (2005) (attached as Ex. 19), *at* http://www.lactaid.com/page.jhtml?id=lactaid/weightloss/studies.inc (last visited May 3, 2005).

[100] Layman D, et al. *A reduced ratio of dietary carbohydrate to protein improves body composition and blood lipid profiles during weight loss in adult women.* J Nutr. 2003; 133: 411-417.

[101] Pereira MA, Jacobs DR, Van Horn L, Slattery ML, Kartashov AI, Ludwig DS. *Dairy consumption, obesity, and the insulin resistance syndrome in young adults.* JAMA. 2002;287:2081-2089.

[102] YOPLAIT, REFERENCES (2005) (attached as Ex. 20), *at* http://www.yoplaitusa.com/health_references.aspx (last retrieved by google.com Sept. 27, 2004). Although the Yoplait Web site currently displays an error message, the google.com search engine provides a copy of the Web site as it appeared on September 27, 2004. The exact same set of references is also available on at least one Web site affiliated with Yoplait. FITNESS MAGAZINE, BOOST YOUR WEIGHT LOSS PLAN. TRY MAKING YOPLAIT LIGHT YOUR PARTNER FOR WEIGHT LOSS (2005) (attached as Ex. 21), *at* http://www.fitnessmagazine.com/yoplait/boost_your_weight_loss_plan3.htm (last visited May 31, 2005).

[103] NATIONAL DAIRY COUNCIL, DAIRY'S ROLE IN WEIGHT MANAGEMENT (2005) (attached as Ex. 22), *at* http://www.nationaldairycouncil.org/nationaldairycouncil/healthyweight/science (last visited May 3, 2005).

[104] Albertson AM, et al. *Ready-to-eat cereal consumption: its relationship with BMI and nutrient intake of children aged 4 to 12 years.* J Am Diet Assoc. 2003;103:1613-1619.

[105] 24/24 MILK YOUR DIET, OVERVIEW OF SCIENCE & ARTICLES (2005) (attached as Ex. 23), *at* http://www.2424milk.com/2424_science_overview.htm (last visited May 17, 2005).

[106] Heaney RP, et al. *Normalizing calcium intake Projected population effects for body weight.* J Nutr. 2003; 133:268S-270S.

[107] Teegarden D, et al. *Calcium intake and reduction in weight or fat mass.* J Nutr. 2003; 133: 249S-251S.

[108] Davies KM, et al. *Calcium intake and body weight.* J Clin Endocrinol Metab. 2000; 85(12):4635-4638.

[109] Davies (2000); Heaney (2003); Teegarden (2003); Parikh SJ, et al. *Calcium intake and adiposity.* Am J Clin Nutr. 2003; 77:281-287; Zemel MB. *Role of dietary calcium and dairy products in modulating adiposity.* Lipids. 2003;38:139-146; Zemel MB, et al. *Regulation of adiposity by dietary calcium.* FASEB J. 2000; 14:1132-1138; St-Onge MP, et al. *Dietary fats, teas, dairy, and nuts. potential functional foods for weight control.* AJCN 2005; 81:7-15.

[110] Zemel (2003); Parikh (2003); Teegarden (2003); Heaney (2003) Davies (2000).

summarize an existing body of literature, but do not add any new data to the body of literature. In fact, FDA does not consider review articles to be part of the body of evidence.[111] Identifying review articles as supporting science is misleading because it exaggerates and distorts the truth to the reasonable consumer, who does not know the difference between a review article and a randomized controlled therapeutic trial.

- *Dairy product manufacturers rely on observational studies that fail to show any causal relationship.* The Yoplait Web site cites Jacqmain (2003) and Lin (2000), both of which are observational and do not indicate any causal relationship between dairy and weight or fat loss. The Lactaid Web site links to the National Dairy Council Web site, which cites a total of 35 studies,[112] 18 of which are observational.[113] Of these 18 observational studies, 7 have been published only in abstract form and 3 are studies of overall food patterns in which dairy consumption is grouped with other eating behaviors that do not directly address the question of whether dairy, calcium, or milk consumption influences body weight or fatness. The Lactaid Web site also links to the "24/24 milk your diet" weight loss plan Web site, which cites 9 observational studies.[114] None of the observational studies cited on these Web sites reported weight loss over time, but instead showed varying smaller amounts of weight *gain* on a dairy-based diet as compared to other diets. Such heavy reliance on studies that fail to show any associated or causal relationship distorts the truth to the reasonable consumer and is misleading.

---

[111] *See* INTERIM EVIDENCE-BASED RANKING SYSTEM FOR SCIENTIFIC DATA, *supra* note 63.

[112] DAIRY'S ROLE IN WEIGHT MANAGEMENT, *supra* note 103.

[113] Barba (2005); Jacqmain (2003); Lin (2000); Loos (2003); Mirmiran (2005); Novotny (2004); Phillips (2003); Skinner (2003); Dicker D, Belnic Y, Goldsmith F, Green M, Nitzan-Kaluski D. *On the relationship between dietary calcium intake, body mass index and waist size.* Presented at the 13th European Congress on Obesity. International Journal of Obesity and Related Metabolic Disorders. 2004; Supplement 1(28):S59. Abstract; Newby PK, Muller D, Hallfrisch J, Qiao N, Andres R, Tucker KL. *Dietary patterns and changes in body mass index and waist circumference in adults.* Am J Clin Nutr. 2003;77:1417-1425; Newby PK, Muller D, Hallfrisch J, Andres R, Tucker KL. *Food patterns measured by factor analysis and anthropometric changes in adults.* Am J Clin Nutr 2004;80:504-513; Drapeau V, Despres JP, Bouchard C, et al. *Modifications in food-group consumption are related to long-term body-weight changes.* Am J Clin Nutr. 2004; 80:29-37; Moore LL, et al. *Dietary predictors of excess body fat acquisition during childhood.* Circulation 2004;109:5, No. 3; Moore LL, Singer M, Bradlee ML, Gao D, Hood M, Ellison RC. *Low intakes of dairy product in early childhood may increase body fat acquisition.* Obes Res. 2003;11:130-OR; Kabrnova K, Braunerova R, Aldhoon B, Hlavaty P, Wagenknecht M, Kunesova M, Parizkova J, Hainer B. *Association of changes in macronutrient and calcium intakes with body weight change in obese subjects.* Presented at the 13th European Congress on Obesity. International Journal of Obesity and Related Metabolic Disorders. 2004; Supplement 1(28):S138. Abstract; Lelovics Z,Tarnavolgyi, G. *Relation between calcium intake and obesity.* Presented at the 13th European Congress on Obesity. International Journal of Obesity and Related Metabolic Disorders. 2004; Supplement 1(28):S169. Abstract; Ochner CN, Lowe MR. *Opposing effects of calcium and caloric intake on weight regain after diet.* Presented at the 13th European Congress on Obesity. International Journal of Obesity and Related Metabolic Disorders. 2004; Supplement 1(28):S143. Abstract; Tsakalou Z, Yannakoulia M, Fotios A, Terzidou M, Kokkevi A, Sidossis L. *Prevalence of obesity/overweight and eating habits in Greek adolescents.* Presented at the 13th European Congress on Obesity. International Journal of Obesity and Related Metabolic Disorders. 2004; Supplement 1(28):S203. Abstract.

[114] Jacqmain (2003); Lin (2000); Moore (2003); Moore (2004); Newby (2003); Newby (2004); Novotny (2004); Phillips (2003); Skinner (2003).